

WHAT IS CLAIMED IS:

1. An intravascular flow modifier (IFM) for use in a vessel, the vessel having an interior surface, the IFM comprising:

an outer layer formed of a strand, said strand being configured as a longitudinally oriented coil of adjacent helical loops extending between a first end and a second end of said outer layer, said outer layer being secured in the vessel by at least some of said helical loops pressing against a portion of the interior surface of the vessel; and

an inner layer formed of a strand, said strand being configured as a longitudinally oriented coil of adjacent helical loops extending between a first end and a second end of said inner layer, at least a portion of said outer layer surrounding at least a portion of said inner layer so that at least some of said loops of said outer layer overlap and contact at least some of said loops of said inner layer.

2. The IFM of claim 1, wherein said strand of said outer layer and said inner layer is a continuous strand.

3. The IFM of claim 2, wherein said continuous strand is made of a biocompatible material.

4. The IFM of claim 1, wherein said strands of said outer and inner layers comprises a high shape memory alloy.

5. The IFM of claim 4, wherein said strands are made of a Nitinol alloy.

6. The IFM of claim 1, wherein said strand of said outer and inner layers have a cross-section, the cross-section being one of circular, oval, rectangle, and triangular.

7. The IFM of claim 1, wherein said second end of said outer layer is anchored proximal to said first end of said inner layer.
8. The IFM of claim 2, wherein said first end of said outer layer is attached to said second end of said inner layer such that said continuous strand forms a loop.
9. The IFM of claim 1, wherein said second end of said outer layer is joined to said first end of said inner layer.
10. The IFM of claim 1, wherein said first end of said outer layer includes means for inhibiting said strand from penetrating through the interior surface of the vessel.
11. The IFM of claim 10, wherein said inhibiting means includes a loop on said first end of said strand.
12. The IFM of claim 1, wherein said second end of said inner layer includes means for inhibiting said strand from penetrating through the interior surface of the vessel.
13. The IFM of claim 12, wherein said inhibiting means includes a loop on said second end of said strand.
14. The IFM of claim 1, wherein said first end of said outer layer and said second end of said inner layer are distal ends relative to an insertion point into the vessel.
15. The IFM of claim 1, wherein said second end of said outer layer and said first end of said inner layer are proximal ends relative to an insertion point into the vessel.
16. The IFM of claim 1, wherein said helical loops of said outer and inner layers are substantially circular.
17. The IFM of claim 1, wherein both said helical loops of said outer and inner layers wind in a predetermined direction.

18. The IFM of claim 1, wherein the number of said helical loops of said outer layer is N, where N is at least two.

19. The IFM of claim 1, wherein the number of said helical loops of said inner layer is M, where M is at least two.

20. The IFM of claim 1, wherein said outer layer is divided into at least a first end portion, a middle portion, and a second end portion along said longitudinally oriented coil, said first end, middle, and second end portions each having a pitch, the pitch of said middle portion being smaller than the pitch of said first end and second end portions.

21. The IFM of claim 20, wherein the pitch of said first end portion provides a gap between said helical loops of between 3 and 7 mm, the pitch of said middle portion provides a gap between said helical loops of between 0.5 and 3 mm, and the pitch of said second end portion provides a gap between said helical loops of between 3 and 7 mm.

22. The IFM of claim 20, wherein said strand of said outer layer has a diameter, the diameter of said strand of said first end and second end portions is smaller than the diameter of said strand of said middle portion.

23. The IFM of claim 22, wherein the diameter of said strand of said outer layer is no greater than .020 inches.

24. The IFM of claim 23, wherein the diameter of said strand of said outer layer comprising said first end and second end portions is between .001 and .002 inches, and the diameter of said strand comprising said middle portion is between .003 and .004 inches.

25. The IFM of claim 1, wherein said outer layer is divided into a first end portion, a middle portion, and a second end portion along said longitudinally oriented coil, said first end, middle, and second end portions each having a pitch, the pitch of said middle portion being larger than the pitch of said first end and second end portions.

26. The IFM of claim 1, wherein said inner layer is divided into at least a first end portion, a middle portion, and a second end portion along said longitudinally oriented coil, said first end, middle, and second end portions each having a pitch, the pitch of said middle portion being smaller than the pitch of said first end and second end portions.

27. The IFM of claim 26, wherein the pitch of said first end portion provides a gap between said helical loops of between 3 and 7 mm, the pitch of said middle portion provides a gap between said helical loops of between 0.5 and 3 mm, and the pitch of said second end portion provides a gap between said helical loops of between 3 and 7 mm.

28. The IFM of claim 26, wherein said strand of said inner layer has a diameter, the diameter of said strand of said first end and second end portions is smaller than the diameter of said strand of said middle portion.

29. The IFM of claim 28, wherein the diameter of said strand of said inner layer is no greater than .020 inches.

30. The IFM of claim 29, wherein the diameter of said strand of said inner layer comprising said first end and second end portions

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35. An intravascular flow modifier (IFM) for use in a vessel, the vessel having an interior surface, the IFM comprising:

an outer layer formed of a strand having a first end, a second end opposite said first end, and a longitudinally oriented coil of adjacent helical loops between said first and second ends, said outer layer being secured in the vessel by at least some of said helical loops pressing against a portion of the interior surface of the vessel; and

an inner layer formed of a strand having a first end, a second end opposite said first end, and a longitudinally oriented coil of adjacent loops between said first and second ends, at least a portion of said outer layer surrounding at least a portion of said inner layer so that at least some of said loops of said outer layer overlap and contact at least some of said loops of said inner layer,

said strand of said outer and inner layers being a continuous strand formed of a high shape memory alloy and having a cross-section, the cross-section being one of circular, oval, rectangle, and triangular, said helical loops of said outer and inner layers being substantially circular, said second end of said outer layer joining said first end of said inner layer, said first end of said outer layer and said second end of said inner layer being distal ends relative to an insertion point into the vessel, said second end of said outer layer and said first end of said inner layer being proximal ends relative to an insertion point into the vessel, said helical loops of said outer and inner layers wind in a predetermined direction.

36. An intracranial intravascular flow modifier (IFM) for use in a cranial vessel, the vessel having an interior surface, the IFM comprising:

an outer layer formed of a strand having a first end, a second end opposite said first end, and a longitudinally oriented coil of adjacent helical loops between said first and second ends, said outer layer being secured in the vessel by at least some of said helical loops pressing against a portion of the interior surface of the vessel; and

an inner layer formed of a strand having a first end, a second end opposite said first end, and a longitudinally oriented coil of adjacent helical loops between said first and second ends, at least a portion of said outer layer surrounding at least a portion of said inner layer so that at least some of said loops of said outer layer overlap and contact at least some of said loops of said inner layer,

said strand of said outer and inner layers being a continuous strand formed of a high shape memory alloy, said helical loops of said outer and inner layers being substantially circular, said second end of said outer layer joining said first end of said inner layer, said first end of said outer layer and second end of said inner layer being distal ends relative to an insertion point into the vessel, said second end of said outer layer and first end of said inner layer being proximal ends relative to an insertion point into the vessel, said IFM having an outside diameter of between about 1.5 and 12 mm.

40. An assembly for an intravascular repair of a defect of a body vessel, the vessel having an interior surface, the assembly comprising:

an elongated first catheter;

an IFM having a deployed configuration when in the vessel at a site of the defect and a pre-deployed configuration for movement through said first catheter;

said IFM including an outer layer formed of a strand, said adjacent helical loops extending between a first end and a second end of said outer layer, once deployed said outer layer being secured in the vessel by at least some of said loops urging against a portion of the interior surface of the vessel, and an inner layer formed of a strand, said strand being configured as a longitudinally oriented coil of adjacent helical loops extending between a first end and a second end of said inner layer, once deployed in the vessel at the site of the defect at least a portion of said outer layer surrounding at least a portion of said inner layer so that at least some of said loops of said outer layer overlap and contact at least some of said loops of said inner layer; and

said first catheter having a proximal end, a distal end, and a central lumen extending axially therethrough, said lumen having a size and shape complementary to the pre-deployed configuration of said IFM such that said IFM is axially slidable therethrough.

41. The assembly of claim 40, further comprising a second catheter having a distal end, a proximal end, and a central lumen extending axially therethrough, said lumen of said second catheter

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having a size and shape complementary to said first catheter such that said first catheter is axially slidable therein, and such that at least a portion of said distal end of said first catheter can be inserted into said lumen of said second catheter at said proximal end and passes through said lumen of said second catheter and exits said second catheter at said distal end.

42. The assembly of claim 41, further comprising a third catheter having a distal end, a proximal end, and a central lumen extending axially therethrough, said lumen of said third catheter having a size and shape complementary to said second catheter such that said second catheter is axially slidable therein, and such that at least a portion of said distal end of said second catheter can be inserted into said lumen of said third catheter at said proximal end and passes through said lumen of said third catheter and exits said third catheter at said distal end.

43. The assembly of claim 40, wherein the vessel is a cranial vessel, and said IFM has a deployed diameter of between about 1.5 and 12 mm.

44. The assembly of claim 40, wherein said strand of said outer and inner layers has a diameter of no greater than about .020 inches.

45. The assembly of claim 40, wherein said first catheter has an outside diameter of between about .010 and about .014 inches.

46. The assembly of claim 40, wherein said first catheter has an inside diameter of between about .004 and about .006 inches.

47. The assembly of claim 41, wherein said second catheter has an outside diameter of approximately 1 mm.

48. The assembly of claim 41, wherein said second catheter has an inside diameter of at least approximately .022 inches.

49. An assembly for an intravascular repair of a defect of a body vessel, the vessel having an interior surface, the assembly comprising:

an IFM having a deployed configuration when in the vessel at a site of the defect and a pre-deployed configuration for movement through the vessel towards the site of the defect;

said IFM including an outer layer formed of a strand, said strand being configured as a longitudinally oriented coil of adjacent helical loops extending between a first end and a second end of said outer layer, once deployed said outer layer being secured in the vessel by at least some of said loops urging against a portion of the interior surface of the vessel, and an inner layer formed of a strand, said strand being configured as a longitudinally oriented coil of adjacent helical loops extending between a first end and a second end of said inner layer, once deployed in the vessel at the site of the defect at least a portion of said outer layer surrounding at least a portion of said inner layer so that at least some of said loops of said outer layer overlap and contact at least some of said loops of said inner layer; and

a means for moving and maintaining said IFM when in the pre-deployed configuration, the outer and inner layers of said IFM taking the deployed configuration when the moving and maintaining means is no longer applied thereto.

50. The IFM of claim 49, wherein the moving and maintaining means comprises an elongated first catheter having a proximal end, a distal end, and a central lumen extending axially therethrough, said lumen having a size and shape complementary to the respective size and shape of said IFM when in the pre-deployed configuration such that said outer and inner layers are axially slidable therein.

51. The IFM of claim 49, further comprising means for disposing said IFM within the vessel.

52. The IFM of claim 51, wherein the disposing means comprises:
an elongated first catheter having a proximal end, a distal end, and a central lumen extending axially therethrough, said lumen having a size and shape complementary to the respective size and shape of said IFM when in the pre-deployed configuration such that said IFM is axially slidable therein; and

an elongated second catheter having a proximal end, a distal end, and a central lumen extending axially therethrough, said lumen having a size and shape complementary to said first catheter such that said first catheter is axially slidable therein, and such that at least a portion of said distal end of said first catheter can be inserted into said lumen of said second catheter at said proximal end and passes through said lumen of said second catheter and exits said second catheter at said distal end.

53. The IFM of claim 49, and further comprising means for selectively varying the gap between said adjacent helical loops of said outer and inner layers.

54. The IFM of claim 53, wherein said selectively varying means comprises:

an elongated first catheter having a proximal end, a distal end, and a central lumen extending axially therethrough, said lumen having a size and shape complementary to the respective size and shape of said IFM when in the pre-deployed configuration such that said IFM is axially slidable therein;

an elongated second catheter having a proximal end, a distal end, and a central lumen extending axially therethrough, said lumen having a size and shape complementary to said first catheter such that said first catheter is axially slidable therein, and such that at least a portion of said distal end of said first catheter can be inserted into said lumen of said second catheter at said proximal end and passes through said lumen of said second catheter and exits said second catheter at said distal end; and

means for controlling axial movement of said IFM when in the pre-deployed configuration through said first catheter and out of said distal end of said first catheter.

55. The IFM of claim 54, wherein said controlling means includes means for controlling the axial movement of said IFM and said first catheter.

56. An assembly for an intravascular repair of a defect of a cranial vessel, the vessel having an interior surface, the assembly comprising:

an elongated first catheter;

an IFM having a deployed configuration when in the vessel at a site of the defect and a pre-deployed configuration for movement through said first catheter;

said IFM including an outer layer formed of a strand, said strand being configured as a longitudinally oriented coil of adjacent helical loops extending between a first end and a second end of said outer layer, once deployed said outer layer being secured in the vessel by at least some of said loops urging against a portion of said interior surface of the vessel, and an inner layer formed of a strand, said strand being configured as a longitudinally oriented coil of adjacent helical loops extending between a first end and a second end of said inner layer, once deployed in the vessel at the site of the defect at least a portion of said outer layer surrounding at least a portion of said inner layer so that at least some of said loops of said outer layer overlap and contact at least some of said loops of said inner layer, said IFM having a deployed diameter of between about 1.5 and about 12 mm;

said first catheter having a proximal end, a distal end, and a central lumen extending axially therethrough, said lumen having an inside diameter of between about .004 and about .006 inches to receive the pre-deployed configuration of said IFM such that said IFM is axially slidable therethrough; and

a second catheter having a distal end, a proximal end, and a central lumen extending axially therethrough, said lumen of said second catheter having an inside diameter of at least about .022 inches to receive said first catheter such that said first

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catheter is axially slidable therein, and such that at least a portion of said distal end of said first catheter can be inserted into said lumen of said second catheter at said proximal end and passes through said lumen of said second catheter and exits said second catheter at said distal end.

57. A method of forming an intravascular flow modifier (IFM) at a pre-selected segment of a vessel, said IFM having a first portion comprising an outer layer of strand and a second portion comprising an inner layer of strand, the vessel having an interior surface, the method comprising the steps of:

moving said IFM through a catheter up to the pre-selected segment of the vessel;

manipulating at least one of said outer layer of strand and said catheter to deploy said outer layer of strand in the pre-selected segment of vessel as a longitudinally oriented coil of adjacent helical loops; and

manipulating at least one of said inner layer of strand and said catheter to deploy said inner layer of strand in the pre-selected segment of vessel as a longitudinally oriented coil of adjacent helical loops within said first portion of said IFM.

58. The method of claim 57, wherein the step of moving includes the step of insulating said IFM within said catheter.

59. The method of claim 57, further comprising the step of inserting said IFM into said catheter prior to the step of moving.

60. The method of claim 59, further comprising the step of elongating said IFM prior to inserting said IFM into said catheter.

61. The method of claim 60, wherein the step of elongating said IFM includes the step of straightening said IFM to a substantially linear configuration.

62. The method of claim 60, wherein said catheter used in the step of moving has a proximal end, a distal end, and a central lumen extending axially therethrough, said lumen having a size and shape complementary to said IFM when elongated such that said first and second portions of said IFM are axially slidable therethrough.

63. The method of claim 59, wherein said catheter used in the step of inserting includes an elongated micro-catheter having a proximal end, a distal end, and a central lumen extending axially therethrough, said lumen having a size and shape complementary to said IFM when elongated such that said IFM is axially slidable therethrough, and the step of inserting further comprises the step of providing an elongated guide catheter having a distal end, a proximal end, and a central lumen extending axially therethrough, said guide catheter being positioned in the vessel with said distal end of said guide catheter being oriented near the pre-selected segment of the vessel, said lumen of said guide catheter having a size and shape complementary to said micro-catheter such that said micro-catheter is axially slidable therethrough.

64. The method of claim 63, further including the step of inserting at least a portion of said distal end of said micro-catheter into said lumen of said guide catheter at said proximal end and passing through said lumen of said guide catheter and

exiting said guide catheter at said distal end prior to the step of moving said IFM.

65. The method of claim 64, wherein the step of inserting further comprises the step of providing an elongated angiographic catheter having a distal end, a proximal end, and a central lumen extending axially therethrough, said angiographic catheter being positioned in the vessel with said distal end of said angiographic catheter being oriented closer to an insertion point into the vessel than said distal end of said guide catheter, said lumen of said angiographic catheter having a size and shape complementary to said guide catheter such that said guide catheter is axially slidable therethrough.

66. The method of claim 65, further including the step of inserting at least a portion of said distal end of said guide catheter into said lumen of said angiographic catheter at said proximal end and passing through said lumen of said angiographic catheter and exiting said angiographic catheter at said distal end prior to the step of moving said IFM.

67. The method of claim 66, further comprising the step of inserting said angiographic catheter into the vessel before inserting said guide catheter containing said micro-catheter into the vessel.

68. The method of claim 67, further comprising the steps of halting the advancement of said angiographic catheter into the vessel and continuing to advance said guide catheter containing said micro-catheter into the vessel.

69. The method of claim 68, further comprising the steps of halting the advancement of said guide catheter into the vessel and continuing to advance said micro-catheter into the vessel.

70. The method of claim 64, wherein the steps of manipulating include the step of selectively varying the spacing between said adjacent helix loops of said outer and inner layers, respectively.

71. The method of claim 60, further comprising the step of expanding said IFM substantially to a pre-elongated diameter during the steps of manipulating.

72. The method of claim 71, wherein the step of expanding said IFM includes the step of warming said strand of said outer layer and said strand of said inner layer.

73. The method of claim 57, wherein the step of manipulating at least one of said outer layer and said catheter includes the step of providing said outer layer with a number of loops where the number is at least two.

74. The method of claim 57, wherein the step of manipulating at least one of said outer layer and said catheter includes the step of providing said outer layer with a single loop.

75. The method of claim 57, wherein the step of manipulating at least one of said inner layer and said catheter includes the step of providing said inner layer with a number of loops where the number is at least two.

76. The method of claim 57, wherein the step of manipulating at least one of said inner layer and said catheter includes the step of providing said inner layer with a single loop.

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77. The method of claim 57, wherein the step of manipulating said first portion of said IFM includes the step of feeding said outer layer out of said catheter to produce a first end portion, a middle portion, and a second end portion along said longitudinally oriented coil, said first end, middle, and second end portions each having a pitch, the pitch of said middle portion being smaller than the pitch of said first end and second end portions.

78. The method of claim 77, wherein the step of feeding includes the step of winding the pitch of said first end portion to provide a gap between said loops of between 3 and 7 mm, the pitch of said middle portion to provide a gap between said loops of between 0.5 and 3 mm, and the pitch of said second end portion to provide a gap between said loops of between 3 and 7 mm.

79. The method of claim 57, wherein the step of manipulating said first portion of said IFM includes the step of pushing said first portion out of said catheter and into the pre-selected segment, said catheter having a proximal end and a distal end relative to an insertion point into the vessel.

80. The method of claim 79, wherein the step of pushing includes pushing said first portion out of said distal end of said catheter while pulling said catheter towards the insertion point into the vessel.

81. The method of claim 79, wherein the step of pushing includes pushing said first portion out of said distal end of said catheter at a predetermined rate while pushing said catheter towards the pre-selected segment of the vessel at a rate slower than the predetermined rate of said second portion.

manipulating at least one of said outer layer of strand and said catheter to deploy said outer layer of strand in the pre-selected segment of vessel as a longitudinally oriented coil of adjacent helical loops; and

manipulating at least one of said inner layer of strand and said catheter to deploy said inner layer of strand in the pre-selected segment of vessel as a longitudinally oriented coil of adjacent helical loops within said first portion of said IFM.

88. The method of claim 87, wherein the step of manipulating said first portion of said IFM includes the step of pushing said first portion out of said catheter and into the pre-selected segment, said catheter having a proximal end and a distal end relative to an insertion point into the vessel.

89. The method of claim 88, wherein the step of pushing includes pushing said first portion out of said distal end of said catheter while pulling said catheter towards the insertion point into the vessel.

90. The method of claim 88, wherein the step of pushing includes pushing said first portion out of said distal end of said catheter at a predetermined rate while pushing said catheter towards the pre-selected segment of the vessel at a rate slower than the predetermined rate of said second portion.

91. The method of claim 87, wherein the step of manipulating said second portion of said IFM includes the step of pushing said second portion out of said catheter and into the pre-selected segment, said catheter having a proximal end and a distal end relative to an insertion point into the vessel.

92. The method of claim 91, wherein the step of pushing includes pushing said second portion out of said distal end of said catheter at a predetermined rate while pushing said catheter towards the pre-selected segment of the vessel at a rate slower than the predetermined rate of said second portion.

93. The method of claim 91, wherein the step of pushing includes pushing said second portion out of said distal end of said catheter while pulling said catheter towards the insertion point into the vessel.

94. A method of forming an IFM at a pre-selected segment of a vessel, the vessel having an interior surface, the method comprising the steps of:

straightening said IFM to a substantially linear configuration;

providing a guide catheter and a micro-catheter, each of said catheters having a distal end, a proximal end, and a central lumen extending axially therethrough;

inserting said micro-catheter into said guide catheter;

inserting said guide catheter into the vessel;

inserting said IFM into said micro-catheter;

positioning said guide catheter in the vessel with the distal end of said guide catheter being oriented between the pre-selected segment of the vessel and an insertion point into the vessel;

advancing at least a portion of said distal end of said micro-catheter through said guide catheter and exiting said guide catheter at said distal end;

moving said IFM through said micro-catheter up to the pre-selected segment of the vessel; and

manipulating said layer of strand and said catheter to deploy said outer layer of strand in the pre-selected segment of vessel as a longitudinally oriented coil of adjacent helical loops.

95. The method of claim 94, further comprising the steps of halting the advancement of said guide catheter into the vessel and continuing to advance said micro-catheter into the vessel.

96. The method of claim 94, wherein the step of manipulating includes the step of selectively varying the spacing between said adjacent helix loops of said layer.

97. The method of claim 94, further comprising the step of expanding said IFM substantially to a pre-elongated diameter during the step of manipulating.

98. The method of claim 94, wherein the step of manipulating includes the step of feeding said layer of strand out of said micro-catheter to produce a first end portion, a middle portion, and a second end portion along said longitudinally oriented coil, said first end, middle, and second end portions each having a pitch, the pitch of said middle portion being smaller than the pitch of said first end and second end portions.

99. The method of claim 94, wherein the step of manipulating includes the step of pushing said layer of strand out of said micro-catheter and into the pre-selected segment, said micro-catheter having a proximal end and a distal end relative to an insertion point into the vessel.

